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EXAMINER	
WILSON, LARRY ROSS	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,810	NEFTEL ET AL.	
	Examiner	Art Unit	
	LARRY R. WILSON	4166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *25 January 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the membrane covering said channel along an oblique plane, preferably at 45° (claim 27), and a lip valve (claim 44), must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the pump race (21), roller separator (12) in Fig. 7, cartridge loader shaft in Fig. 16, as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

4. The drawings are objected to because Figs. 2-18, 7a, 14a, 21, 23, 24a, 24b, 24c, 26-30 and 32 are too dark to read, making it very difficult to determine the details claimed.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The abstract of the disclosure is objected to because it is a verbatim recitation of Claim 1 containing legal phraseology and does not apprise the public of the nature and gist of the invention claimed. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6-7, 22-25, 27-29, 32-33, 46, 47, and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding claim 6, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

9. Regarding claim 22, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

10. Claims 24 and 47 contain the trademark/trade names Kraton™, Santoprene™, polyurethane™, Pebax™ or Biopure™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe thermoplastic elastomers and polyolefin resins and, accordingly, the identification/description is indefinite.

11. Claim 27 recites the limitation "said membrane" in line 2. There is insufficient antecedent basis for this limitation in the claim.

12. Regarding claim 28, 32, and 46, the phrase "e.g (for example)" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

11. Claim 65 provides for the use of a system as defined in claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

12. Claim 65 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 9, 17, 19-21, 26, 30, 41-45, 48, 54, 56-58, 61, 64, and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,350,357 to Dean Kamen, et al., (Kamen).

In Reference to Claim 1

Kamen teaches:

A system for performing fluid administration on a patient comprising:

- a liquid pump (col. 7, lines 44-46),

- a liquid distribution system connected to said pump in such a way that liquid can flow from the liquid distribution system to the pump and vice versa (col. 7, lines 52-54),

- liquid supply means (Fig. 1, #36) for supplying liquid to a patient via said liquid distribution system and said pump,

- a patient conduit (Fig. 1, #18) adapted for connecting said liquid distribution system to a patient,

characterized by the fact that said liquid distribution system comprises two distinct hub chambers which are separated by a space, the first hub chamber (Fig. 8A, #F9) including at least one liquid supply port (Fig. 8A, #33) with dedicated valve means (Fig. 8A, #V6), one patient port (Fig. 8A, # 35) with

dedicated valve means (Fig. 8A, #V7) and one pump inlet (Fig. 8A, #66(2)), the second hub chamber (Fig. 8A, #F8) including at least, one patient port (Fig. 8A, #35)) or warmer port with dedicated valve means (Fig. 8A, #V8) and one pump outlet (Fig. 8A, #66(1)), said system furthermore comprising control means arranged to close said patient port of the first hub chamber (Fig. 33, #V7) when said liquid supply port (Fig. 8A, #33) is open and vice versa (Fig. 8A, #V6, V8).

In Reference to Claim 2

Kamen teaches:

System according to claim 1 (see rejection above) wherein said second hub chamber (Fig. 8A, #F8) furthermore includes at least one drain port (Fig. 8A, #29) with dedicated valve means (Fig. 8A, #V4), said control means being also arranged to close said patient port (Fig. 8A, #35) of the second hub chamber (Fig. 8A, #F8) when said drain port (Fig. 8A, #29) is open and vice versa.

In Reference to Claim 8

Kamen teaches:

A system according to claim 1 (see rejection above) wherein said first hub chamber (Fig. 8A, #F9) includes several liquid supply ports (Fig. 8A, #31, 33) with respective valve means (Fig. 8A, #V5, V6).

In Reference to Claim 9

Kamen teaches:

A system according to claim 8 (see rejection above) wherein said liquid supply ports (Fig. 8A, #31, 33) are connected to respective liquid supply means having each a different kind of liquid (Fig. 1, #20 & col. 35, lines 65-68).

In Reference to Claim 17

Kamen teaches:

A system according to claim 1 (see rejection above) wherein said liquid pump (Fig. 8A, #P1, P2) and said liquid distribution system (Fig. 8A, #24) are fixed together to form a single cartridge (col. 7, lines 43-46).

In Reference to Claim 19

Kamen teaches:

A system according to claim 19 (see rejection above) wherein all hub chambers, including said ports and ports, are made within one single part (col. 7, lines 37-38, 43-44).

In Reference to Claim 20

Claim 20 is a product-by-process claim. This claim is not limited to manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.

Kamen teaches:

A system according to claim 19 (see rejection above) wherein said single part is an injected part of plastic material (col. 7, lines 37-38).

In Reference to Claim 21

Kamen teaches:

A system according to claim 1 (see rejection above) wherein each hub chamber (Fig. 8A, #F9, F8) is closed with an upper wall made of a flexible membrane (Fig. 8, #59, 61), said membrane including valve elements (Fig. 8C, #V_N) situated above each of said port or port with valve means (Fig. 8C, #68), said valve elements (Fig. 8C, #V_N) being designed to close said port or port when the membrane (Fig. 8C, #59, phantom lines) moves downwardly.

In Reference to Claim 26

Kamen teaches:

A system according to claim 21 (see rejection above) wherein said membrane extends in such a way that it also covers said liquid pump (Fig. 8, #59, 61).

In Reference to Claim 30

Kamen teaches:

A system according to claim 1 (see rejection above) wherein said liquid distribution system (Fig. 8A, #24) includes liquid tight joints (Fig. 8C, #f) arranged in such a manner that they allow a liquid tight connection between said liquid distribution system and a membrane situated on it (col. 7, lines 40-42).

In Reference to Claim 41

Kamen teaches:

A system according to claim 1 (see rejection above) comprising a cartridge loading mechanism (col. 12, lines 65-68 and col. 13, lines 1-2) which allows a tight connection between the membrane (col. 13, lines 3-4) and the valves (col. 13, lines 17-21) and the liquid distribution system (Fig. 15B, #24).

In Reference to Claim 42

Kamen teaches:

A system according to claim 1 (see rejection above) comprising flow blocking means (Fig. 16A, #144, 148) adapted to block the flow towards or from the liquid distribution system (col. 14, line 59) when this latter one is released out of the system (col. 14, lines 49-50).

In Reference to Claim 43

Kamen teaches:

A system according to claim 42 wherein said blocking means is a mechanical clamp situated on the patient line (Fig. 1, #40).

In Reference to Claim 44

Kamen teaches:

A system according to claim 42 (see rejection above) wherein said blocking means is a lip valve (Fig. 16A, #144, 148) situated on the patient line (col. 14, line 59), the system furthermore comprises a movable pin (Fig. 16B, #138) adapted to open said lip valve when the liquid distribution system is released out of the system col. 14, lines 25-29).

In Reference to Claim 45

Kamen teaches:

A system according to claim 21 (see rejection above) comprising a molded frame (Fig. 13, #102) adapted to cover the space between said hub chambers (Fig. 13,

#122), each space above said hub chambers being covered by a flexible membrane (Fig. 8, #59, 61).

In Reference to Claim 48

Claim 48 is a product-by-process claim. This claim is not limited to manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.

Kamen teaches:

A system according to claim 45 (see rejection above) wherein said frame (Fig. 13, #102), membrane (Fig. 8, #59, 61) and liquid distribution system (Fig. 8A, #24) are obtained by overmolding technique.

In Reference to Claim 54

Kamen teaches:

A liquid distribution system (Fig. 8A, #24) for a system performing fluid administration on a patient (col. 38, line 1) as defined in claim 1.

In Reference to Claim 56

Kamen teaches:

Method of use of the system as defined in claim 1 (see rejection above) wherein said patient port (Fig. 33, V7) is closed when said liquid supply port (Fig. 33, #33) is open and vice versa (Fig. 34, #V6, V8).

In Reference to Claim 57

Kamen teaches:

Method according to claim 56 (see rejection above) wherein the pressure is always maintained positive with respect to the drain (col. 2, lines 66-68 – col. 3, lines 1-2).

In Reference to Claim 58

Kamen teaches:

Method according to claim 56 (see rejection above) wherein said liquid is always pumped in the same direction (col. 2, lines 58-63).

In Reference to Claim 61

Kamen teaches:

Method according to claim 56 (see rejection above) wherein the drain phase is a function of the drain speed (col. 34, lines 45-51), said drain phase being ended when the speed is reaching a certain value based on the patient peritoneal cavity pressure measurement (col. 35, lines 55-57).

In Reference to Claim 64

Kamen teaches:

Method according to claim 56 (see rejection above) consisting in the use of a low Natrium concentration liquid for the last exchange cycle to improve ultra-filtration (col. 35, lines 65-68 - col. 36, lines 1-2).

Changing the dextrose concentration is known to increase ultrafiltration, similar to changing the Natrium concentration but without the increase in ionic concentration of the solution, which could lead to alterations in the electrical properties of the cells of the peritoneum.

In Reference to Claim 65

Kamen teaches:

Use of a system as defined in claim 1 (see rejection above) for peritoneal dialysis (col. 38, line 1).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 3, 4, 5, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of U.S. Patent no. 5,437,629 to Milton H. Goldrath (Goldrath).

In Reference to Claim 3

Kamen teaches:

A system according to claim 1 (see rejection above) wherein said liquid distribution system (Fig. 8A, #24)

However, Kamen does not teach:

said liquid distribution system only includes two hub chambers.

Goldrath teaches:

said liquid distribution system only includes two hub chambers (Fig. 2, #12, Fig. 3, #37 & col. 5, lines 37-39).

It would have been obvious to one skilled in the art at the time of the invention to have used the chambers of Goldrath in the peritoneal dialysis apparatus of Kamen in order to collect the drained solution (col. 3, lines 17-18) implicitly taught by Goldrath.

In Reference to Claim 4

Kamen teaches:

> A system according to claim 1 (see rejection above) furthermore comprising a warmer system (Fig. 9, #74),…
>
> said patient port (Fig. 8A, #35) of the second hub chamber (Fig. 8A, #F8) being connected to said warmer port (Fig. 8A, #27) via said warmer system (Fig. 9, #74).

However, Kamen does not teach:

> a cavity including a warmer port and a patient port

Goldrath teaches:

> a cavity (Fig. 2, #24) including a warmer port (Fig. 2, #22) and a patient port (Fig. 2, #26).

It would have been obvious to one skilled in the art at the time of the invention to have included the warmer port and cavity of Goldrath in the peritoneal dialysis apparatus of Kamen in order to maintain the solution at the desired temperature (col. 2, line 68 - col. 3, line 1).

In Reference to Claim 5

Kamen teaches:

A system according to claim 4 (see rejection above) wherein said warmer system (Fig. 9, #74)

However, Kamen does not teach:

is a warmer in-line.

Goldrath teaches:

is a warmer in-line (col. 6, lines 21-22).

It would have been obvious to one skilled in the art at the time of the invention to have put the warmer of Goldrath in-line with the infusion pathway of Kamen in order to heat the solution as needed and reduce setup time.

In Reference to Claim 10

Kamen teaches:

A system according to claim 1 (see rejection above)

However, Kamen does not teach:

wherein said liquid pump is a peristaltic pump.

Goldrath teaches:

wherein said liquid pump is a peristaltic pump (Fig. 2, #36 & col. 4, lines 24-27).

It would have been obvious to one skilled in the art at the time of the invention to have used the peristaltic pump of Goldrath in the peritoneal dialysis apparatus of Kamen in order to provide continuous infusion as implicitly taught by Goldrath.

In Reference to Claim 11

Kamen teaches:

A system according to claim 10 (see rejection above)

However, Kamen does not teach:

wherein said peristaltic pump is unidirectional.

Goldrath teaches:

wherein said peristaltic pump is unidirectional (col. 4, lines 23-27).

It would have been obvious to one skilled in the art at the time of the invention to have used the peristaltic pump of Goldrath in the peritoneal dialysis apparatus of Kamen in a unidirectional manner in order to prevent backflow of dialysis solution into the patient as implicitly taught by Kamen.

18. Claims 6, 7, 40, 47, 49, 51, 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of European Patent Application Publication EP 1 195 171 A2 to Suzuki, Minoru et al. (Suzuki).

In Reference to Claim 6

Kamen teaches:

A system according to claim 5 (see rejection above)

However, Kamen does not teach:

wherein said warmer in-line comprises a warming plate contained therein, such warming plate being covered by a warming pouch like a sock.

Suzuki teaches:

wherein said warmer in-line comprises a warming plate (Fig. 7, #91, 92, 93) contained therein, such warming plate being covered by a warming pouch like a sock.

It would have been obvious to one skilled in the art at the time of the invention to have included the warming plates of Suzuki in the peritoneal dialysis apparatus of Kamen in order to improve heating efficiency of the dialysis fluid (col. 12, lines 50-52) as explicitly taught by Suzuki.

In Reference to Claim 7

Kamen teaches:

A system according to claim 6 (see rejection above)

However, Kamen does not teach:

wherein said warming pouch is composed of a liquid channel which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate.

Suzuki teaches:

wherein said warming pouch is composed of a liquid channel (Fig. 7, #831, 832) which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate (col. 8, lines 25-28).

It would have been obvious to one skilled in the art at the time of the invention to have included the meandering liquid channel of Suzuki in the peritoneal dialysis apparatus of Kamen in order to reliably heat the dialysis fluid (col. 8, lines 27-28) as explicitly taught by Suzuki.

In Reference to Claim 40

Kamen teaches:

A system according to claim 1 wherein said liquid distribution system (Fig. 8A, #24)

However, Kamen does not teach:

includes an air sensor situated on the patient conduit side.

Suzuki teaches:

includes an air sensor (Fig. 2, #14) situated on the patient conduit side (Fig. 2, #33 & col. 13, lines 17-19).

It would have been obvious to one skilled in the art at the time of the invention to have added the air sensor of Suzuki to the peritoneal dialysis apparatus of Kamen in order to detect "bubbles on the inlet" side (col. 13, lines 18-19) as explicitly taught by Suzuki.

In Reference to Claim 47

Kamen teaches:

A system according to claim 45 (see rejection above) wherein said molded frame (Fig. 13, #102)

However, Kamen does not teach:

the frame is at least partially made of silicone, Kraton TM, Polyurethane TM, Pebax TM or Biopure TM.

Suzuki teaches:

the frame is at least partially made of silicone, Kraton TM, Polyurethane TM, Pebax TM or Biopure TM (col. 9 lines 56-58 and col. 10, lines 1-10).

It would have been obvious to one skilled in the art at the time of the invention to have chosen the material of Suzuki for the peritoneal dialysis apparatus of Kamen in order to

improve the quality and reduce the costs of the cassette (col. 9, lines 38-40) as explicitly taught by Suzuki.

In Reference to Claim 49

Kamen teaches:

A system according to claims 21 (see rejection above)

However, Kamen does not teach:

using a double layer membrane adapted to prevents spallation or particule release into the fluid during use.

Suzuki teaches:

using a double layer membrane (col. 10, lines 10-12) adapted to prevents spallation or particule release into the fluid during use.

It would have been obvious to one skilled in the art at the time of the invention to have used the double layer membrane of Suzuki in the peritoneal dialysis apparatus of Kamen in order to improve the quality of the cassette as implicitly taught by Suzuki.

In Reference to Claim 51

Kamen teaches:

A system according to claim 21 (see rejection above) … which covers and holds the membrane (Fig. 8, #59, 61),

However, Kamen does not teach:

furthermore comprising a rigid plate … said rigid plate comprising holes adapted to let moving elements passing through.

Suzuki teaches:

furthermore comprising a rigid plate (Fig. 4, #812) … said rigid plate (Fig. 4, #812) comprising holes (Fig. 5, 81b) adapted to let moving elements passing through (col. 10, lines 15-18).

It would have been obvious to one skilled in the art at the time of the invention to have included the rigid plate of Suzuki in the peritoneal dialysis apparatus of Kamen in order to allow reliable and easy loading of a cassette by anyone (col. 3, lines 26-28) as explicitly taught by Suzuki.

In Reference to Claim 52

Kamen teaches:

A system according to claim 51 (see rejection above)

However, does not teach:

wherein said rigid plate includes pins situated on the membrane side, said pins being adapted to be fixed

Suzuki teaches:

wherein said rigid plate (Fig. 4, #812) includes pins (Fig. 4) situated on the membrane side (Fig. 4, #811), said pins being adapted to be fixed (col. 9, lines 15-17) on the liquid distribution system (Kamen Fig. 8A, #24).

It would have been obvious to one skilled in the art at the time of the invention to have included the pins of Suzuki in the peritoneal dialysis apparatus of Kamen in order to secure the fluid distribution system in a cassette unit as implicitly taught by Suzuki.

19. Claims 12, 35-39, 50, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of U.S. Patent No. 4,758,228 to David R. Williams (Williams).

In Reference to Claim 12

Kamen teaches:

A system according to claim 1 (see rejection above) wherein said liquid pump (Fig. 8A, #P1, P2)

However, Kamen does not teach:

the liquid pump is composed of a tubing and rolling surface on which the tubing is compressed once the cartridge is inserted into a pumping device containing rollers.

Williams teaches:

the liquid pump is composed of a tubing (Fig. 2A, #36) and rolling surface on which the tubing is compressed (Fig. 2A, #46) once the cartridge is inserted into a pumping device containing rollers (col. 4, lines 53-56).

It would have been obvious to one skilled in the art at the time of the invention to have included the peristaltic pump of Williams in the peritoneal dialysis apparatus of Kamen in order to provide a peristaltic pump where variations in the administration set are minimized (col. 2, lines 9-12) as explicitly taught by Williams.

In Reference to Claim 35

Kamen teaches:

A system according to claim 21 (see rejection above) wherein said membrane (Fig. 8, #59, 61)

However, Kamen does not teach:

said membrane contains a portion which is forming part of a pressure sensor.

Williams teaches:

> said membrane contains a portion (Fig. 10, #140) which is forming part of a pressure sensor (col. 3, lines 4-5).

It would have been obvious to one skilled in the art at the time of the invention to have included the pressure sensor of Williams in the membrane of Kamen in order to provide an inexpensive and very accurate pressure sensor (col. 2, lines 13-15) as explicitly taught by Williams.

In Reference to Claim 36

Kamen, as modified by Williams, teaches:

> A system according to claim 35 (see rejection above)

With Williams further teaches the limitation of:

> wherein the active area of said pressure sensor (Fig. 11A, #168A & Fig. 11B, #168B) is designed to be more flexible than the remaining area (col. 8, lines 55-58).

It would have been obvious to one skilled in the art at the time of the invention to have included the pressure sensor of Williams in the peritoneal dialysis apparatus of Kamen in order to provide very accurate pressure sensor (col. 2, lines 13-15) in cassette as explicitly taught by Williams.

In Reference to Claim 37

Kamen, as modified by Williams, teaches:

> A system according to claim 35 (see rejection above)

With Williams further teaches the limitation of:

wherein said pressure sensor has the shape of a disc (Fig. 10, #148, 150) of which the periphery is gripped (Fig. 11B, #168B), said disc furthermore comprising an annular ply (Fig. 10, #148, 150).

It would have been obvious to one skilled in the art at the time of the invention to have included the disc shape of Williams in the peritoneal dialysis apparatus of Kamen in order to sense pressure in a circular tube as implicitly taught by Williams.

In Reference to Claim 38

Kamen, as modified by Williams, teaches:

A system according to claim 35 (see rejection above)…independently from said hub chambers (Fig. 8A, #F9, F8).

With Williams further teaches the limitation of:

wherein said pressure sensor is situated on the patient line (col. 7, lines 58-63)

It would have been obvious to one skilled in the art at the time of the invention to have included a pressure sensor on the patient line of Williams in the peritoneal dialysis apparatus of Kamen in order to indicate to the operator or to signal an alarm (col. 3, lines 16-17) as explicitly taught by Williams.

In Reference to Claim 39

Kamen, as modified by Williams, teaches:

A system according to claim 35 (see rejection above)

With Williams further teaches the limitation of:

comprising a second pressure sensor (Fig. 10, #148), said second pressure sensor being in connection with the first hub chamber (Fig. 13, #144B, 146B).

It would have been obvious to one skilled in the art at the time of the invention to have added a pressure sensor of Williams on the first hub chamber of Kamen in order to indicate to the operator or signal an alarm (col. 3, lines 16-17) as explicitly taught by Williams.

In Reference to Claim 50

Kamen teaches:

A system according to claim 1 (see rejection above)

However, Kamen does not teach:

furthermore comprising a window for detecting correct positioning of the tube.

Williams teaches:

furthermore comprising a window for detecting correct positioning of the tube (col. 2, lines 32-38 & col. 10, lines 32-37).

It would have been obvious to one skilled in the art at the time of the invention to have included the window of Williams in the peritoneal dialysis apparatus of Kamen in order to ensure correct installation of the cassette as implicitly taught by Williams.

It is inherent that when installing the tube and then rotating the pump knob to return the rollers to the pumping position the "first cutout" could function as window.

In Reference to Claim 55

Kamen, as modified by Williams teaches:

for a system for performing fluid administration on a patient (Kamen col. 38, line 1) as defined in claim 35 (see rejection above).

With Williams further teaches the limitation of:

a pressure sensor (Fig. 10, #140)

It would have been obvious to one skilled in the art at the time of the invention to have further added the pressure sensor of Williams to the peritoneal dialysis apparatus of Kamen, as modified by Williams, in order to indicate to the operator or to signal an alarm (col. 3, lines 16-17) as explicitly taught by Williams.

20. Claims 15 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of U.S. Patent No. 5,683,233 to Ahmad-Maher Moubayed et al. (Moubayed).

In Reference to Claim 15

Kamen teaches:

A system according to claim 1 wherein said liquid pump (Fig. 8A, #P1, P2)

However, Kamen does not teach:

the liquid pump comprises a flexible or partially flexible channel and a series of movable finger elements successively situated above said channel, each finger element being movable along a direction which is substantially perpendicular to said channel, all finger elements being adapted to induce a peristaltic movement along said channel.

Moubayed teaches:

the liquid pump comprises a flexible or partially flexible channel (Fig. 1, #28) and a series of movable finger elements successively situated above said channel (Fig. 1, #48), each finger element being movable along a direction which is substantially perpendicular to said channel (Fig. 1), all finger elements being adapted to induce a peristaltic movement along said channel (col. 2, lines 49-62).

It would have been obvious to one skilled in the art at the time of the invention to have added the linear peristaltic pump of Moubayed in the peritoneal dialysis apparatus of Kamen in order to "accommodate a greater range of tube wall thicknesses (col. 2, lines 24-25) as explicitly taught by Moubayed.

In Reference to Claim 16

Kamen teaches:

A system according to claim 15 (see rejection above)

However, Kamen does not teach:

wherein each finger element comprises a convex basis adapted to conform with the channel inner surface and a shaft adapted to be linked to an actuator.

Moubayed teaches:

wherein each finger element comprises a convex basis (Fig. 2, #62) adapted to conform with the channel inner surface (col. 3, lines 53-55) and a shaft adapted to be linked to an actuator (Fig. 1, #48).

It would have been obvious to one skilled in the art at the time of the invention to have included the rounded pinch finger of Moubayed in the peritoneal dialysis apparatus of Kamen in order to "substantially eliminate damage to the tube" (col. 2, line 26) as explicitly taught by Moubayed.

21. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Williams, as applied to claim 12 above, and further in view of Moubayed.

In Reference to Claim 27

Kamen, as modified by Williams, teaches:

A system according to claim 12 (see rejection above) wherein said liquid pump (Fig. 8A, #P1, P2)

But does not teach the liquid pump comprises a flexible or partially flexible channel, said membrane covering said channel along an oblique plane, preferably at 45°, in order to allow a peristaltic movement induced by rollers or similar elements.

Moubayed teaches:

comprises a flexible or partially flexible channel (Fig. 1, #28), said membrane covering said channel along an oblique plane (col. 3, line 26), preferably at 45°, in order to allow a peristaltic movement induced by rollers or similar elements (col. 2, 49-62).

It would have been obvious to one skilled in the art at the time of the invention to have included the flexible channel and membrane of Moubayed in the peritoneal dialysis apparatus of Kamen, as modified by Williams, in order to avoid wall erosion or spallation causing particulate matter to end the fluid stream as implicitly taught by Moubayed. The membrane covers the channel and is along an oblique plane since the tube passes through a curvilinear peristaltic pump race.

In Reference to Claim 28

Kamen, as modified by Williams, teaches:

A system according to claim 27 (see rejection above)

But does not teach a system comprising individual actuators or a cam (e.g. a disc with a vawe) adapt to induce a peristaltic movement.

Moubayed teaches:

comprising individual actuators (Fig. 1, #48) or a cam (e.g. a disc with a vawe) (Fig. 1, #30) adapt to induce a peristaltic movement (col. 2, lines 49-62).

It would have been obvious to one skilled in the art at the time of the invention to have included the cam of Moubayed in the peritoneal dialysis apparatus of Kamen, as modified by Williams, in order to extend and retract the pump fingers (col. 4, lines 2-3) as explicitly taught by Moubayed.

22. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Williams and Moubayed, as applied to claim 28 above, and further in view of U.S. Patent No. 2,684,829 to Rolland McFarland Jr. (McFarland).

In Reference to Claim 29

Kamen, as modified by Williams and Moubayed, teaches:

A system according to claim 28 (see rejection above) wherein said individual actuators are adapted to be actuated by fingers (Moubayed Fig. 1, #30)

But does not teach, the actuators are actuated by fingers clipped to the membrane

McFarland teaches:

which are clipped (Fig. 6, #39) to said membrane.

It would have been obvious to one skilled in the art at the time of the invention to have included the clip of McFarland in the peritoneal dialysis apparatus of Kamen, as modified by Williams and Moubayed, in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (co1. 1, lines 30-34) as implicitly taught by McFarland.

23. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Williams, as applied to claims 12 above, and further in view of U.S. Patent No. 4,530,647 to Fumio Uno (Uno).

In Reference to Claim 13

Kamen, as modified by Williams, teaches:

> A system according to claim 12 (see rejection above) where said rollers (Williams col. 4, lines 53-56)

But does not teach a system where said rollers are of a conical shape in such a way as to be self inserted in the pump race, i.e. without any other mechanism.

Uno teaches:

> are of a conical shape (Fig. 2, #5, 5') in such a way as to be self inserted in the pump race (col. 1, lines 42-44), i.e. without any other mechanism.

It would have been obvious to one skilled in the art at the time of the invention to have included the conical rollers of Uno in the peritoneal dialysis apparatus of Kamen, as modified by Williams, in order to replace the pump tube due to wear out (col. 1, lines 62-63) as explicitly taught by Uno.

24. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen, as modified by Williams, as applied to claims 12, 35-39, and 55 above, and further in view of U.S. Patent No. 5,840,069 to Reginald D. Robinson (Robinson).

In Reference to Claim 14

Kamen, as modified by Williams, teaches:

A system according to claim 12 (see rejection above) where said rollers (Williams col. 4, lines 53-56)

But does not teach a system where said rollers are of a spherical shape.

Robinson teaches:

are of a spherical shape (Fig. 1, #62, 63 & col. 2, lines 19-20).

It would have been obvious to one skilled in the art at the time of the invention to have used the spherical rollers of Robinson in the peritoneal dialysis apparatus of Kamen, as modified by Williams, in order to produce a highly accurate peristaltic pump and minimize the necessary machining (col. 1, lines 44-46) as explicitly taught by Robinson.

25. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of U.S. Patent No. 5,478,211 to Dominiak et al. (Dominiak).

In Reference to Claim 18

Kamen teaches:

A system according to claim 17 wherein said liquid pump (Fig. 8A, #P1, P2) is fixed to said liquid distribution system (Fig. 8A, #24 & col. 7, lines 43-46)

However, Kamen does not teach:

by vibration attenuation means in order to minimize the vibration on the liquid distribution system when the pump is operating.

Dominiak teaches:

by vibration attenuation means (col. 17, lines 29-32) in order to minimize the vibration on the liquid distribution system when the pump is operating.

It would have been obvious to one skilled in the art at the time of the invention to have included the vibration attenuation means of Dominiak in the peritoneal dialysis apparatus of Kamen in order to increase patient comfort as implicitly taught by Dominiak.

26. Claims 31, 34, 46, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of U.S. Patent No. 4,828,545 to Paul Epstein, et al. (Epstein).

In Reference to Claim 31

Kamen teaches:

A system according to claim 21 (see rejection above) wherein said membrane (Fig. 8, #59, 61)

However, Kamen does not teach:

contains protruding elements designed for a liquid tight connection between said hub chambers.

Epstein teaches:

contains protruding elements (Fig. 4C, #250, 262, 263) designed for a liquid tight connection between said hub chambers (col. 16, lines 42-46).

It would have been obvious to one skilled in the art at the time of the invention to have included the protruding elements of Epstein in the peritoneal dialysis apparatus of Kamen in order to provide a seal to prevent fluid flow (col. 16, lines 45-46) as explicitly taught by Epstein.

In Reference to Claim 34

Kamen teaches:

A system according to claim 21 (see rejection above) wherein said membrane (Fig. 8, #59, 61)

However, Kamen does not teach:

is press-fitted along its external border to the liquid distribution system, the membrane being furthermore held by a frame.

Epstein teaches:

is press-fitted (Fig. 4D, Fig. 4E, #198) along its external border to the liquid distribution system (Fig. 4A, #194), the membrane (Fig. 4C, #198) being furthermore held by a frame (Fig. 4E, #196).

It would have been obvious to one skilled in the art at the time of the invention to have included the press-fit and frame of Epstein in the peritoneal dialysis apparatus of Kamen in order to create a "fluid tight sealing engagement" (col. 15, lines 44-45) as explicitly taught by Epstein.

In Reference to Claim 46

Kamen teaches:

A system according to claim 45 (see rejection above) wherein said molded frame (Fig. 13, #102)

However, Kamen does not teach:

is fixed to said liquid distribution system, e.g. by ultrasound, laser welding, gluing or thermal bonding.

Epstein teaches:

is fixed to said liquid distribution system (Fig. 4E, #196), e.g. by ultrasound, laser welding, gluing or thermal bonding (col. 16, lines 61-63).

It would have been obvious to one skilled in the art at the time of the invention to have included the fixed frame liquid distribution system of Epstein in the peritoneal dialysis apparatus of Kamen in order to secure in fluid tight sealing engagement (col. 16, lines 62-63) as explicitly taught by Epstein.

In Reference to Claim 59

Kamen teaches:

Method according to claim 56 (see rejection above) … entering and exiting the liquid distribution system (Kamen Fig. 8A, #24)

However, Kamen does not teach:

consisting of sensing the liquid pressure entering and exiting … and, if necessary, correct the pump flow rate in accordance with the pressure difference.

Epstein teaches:

consisting of sensing the liquid pressure (Fig. 1, #40) … and, if necessary, correct the pump flow rate in accordance with the pressure difference (col. 21, lines 7-10).

It would have been obvious to one skilled in the art at the time of the invention to have added the flow rate control method of Epstein in the peritoneal dialysis apparatus of Kamen in order to detect a "variation between actual and intended infusate volume" (col. 3, lines 39-40) as explicitly taught by Epstein.

27. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of U.S. Patent No. 4,952,372 to Bernhard Huber (Huber).

In Reference to Claim 60

Kamen teaches:

Method according to claim 56 (see rejection above)

However, Kamen does not teach:

consisting in regulating the pump flow rate according to a known predetermined alteration of the flow rate by aging of the tubing.

Huber teaches:

consisting in regulating the pump flow rate according to a known predetermined alteration of the flow rate by aging of the tubing (col. 6, lines 16-20).

It would have been obvious to one skilled in the art at the time of the invention to have included the tubing age compensation method of Huber in the peritoneal dialysis apparatus of Kamen in order that "delivery is independent of aging and external influences" (col. 6, lines 19-20) as explicitly taught by Huber.

28. Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of U.S. Patent No. 4,586,920 to Alan M. Peabody (Peabody).

In Reference to Claim 62

Kamen teaches:

Method according to claim 56 (see rejection above)

However, Kamen does not teach:

wherein the peritoneal volume filled during a cycle is a function of the intra-peritoneal pressure.

Peabody teaches:

wherein the peritoneal volume filled during a cycle is a function of the intra-peritoneal pressure (col. 5, lines 51-55).

It would have been obvious to one skilled in the art at the time of the invention to have included the pressure control method of Peabody in the peritoneal dialysis apparatus of Kamen in order to increase dialysis efficiency as explicitly taught by Peabody (col. 2, lines 22-25).

In Reference to Claim 63

Kamen teaches:

Method according to claim 62 (see rejection above)

However, Kamen does not teach:

wherein the peritoneal cavity is partially emptied as soon as the pressure has reached a predefined threshold.

Peabody teaches:

wherein the peritoneal cavity is partially emptied as soon as the pressure has reached a predefined threshold (col. 5, lines 11-19).

It would have been obvious to one skilled in the art at the time of the invention to include the pressure control method of Peabody in the peritoneal dialysis apparatus of Kamen in order to minimize the danger of infection as explicitly taught by Peabody (col. 2, lines 29-30).

29. Claims 22, 32, 33, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of U.S. Patent No. 2,684,829 to Rolland McFarland Jr. (McFarland).

In Reference to Claim 22

Kamen teaches:

> A system according to claim 1 (see rejection above) wherein each hub chamber (Fig. 8A, #F8, F9) is closed with an upper wall made of a flexible membrane (Fig. 8, #59, 61),

However, Kamen does not teach:

> said membrane including clipping means adapted to clip elements such as valve actuating or finger elements.

McFarland teaches:

> said membrane including clipping means (Fig. 6, #39) adapted to clip elements such as valve actuating (Fig. 6, #33) or finger elements.

It would have been obvious to one skilled in the art at the time of the invention to have added the clip elements of McFarland to the peritoneal dialysis apparatus of Kamen in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (col. 1, lines 30-34) as implicitly taught by McFarland.

In Reference to Claim 32

Kamen teaches:

> A system according to claim 21 (see rejection above) wherein each of said valve elements (Fig. 8C, #V_N)

However, Kamen does not teach:

is designed to be clipped to an actuator (34), e.g. an electromagnetic actuator or a magnet, arranged above said membrane (13).

McFarland teaches:

is designed to be clipped (Fig. 6, #39) to an actuator (Kamen Fig. 13, #VA1), e.g. an electromagnetic actuator or a magnet, arranged above said membrane (Kamen Fig. 7).

It would have been obvious to one skilled in the art at the time of the invention to have included the clip of McFarland in the peritoneal dialysis apparatus of Kamen in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (col. 1, lines 30-34) as implicitly taught by McFarland.

In Reference to Claim 33

Kamen teaches:

A system according to claim 32 (see rejection above) wherein each of said valve elements (Fig. 8C, #V_N)

However, Kamen does not teach:

comprises a cavity designed to receive and hold the plunger of an actuator, said cavity having an height which substantially corresponds to at least the valve displacement.

McFarland teaches:

comprises a cavity (col. 4, lines 47-48) designed to receive and hold the plunger of an actuator (Fig. 6, #33), said cavity having an height which substantially corresponds to at least the valve displacement (col 4, lines 48-54).

It would have been obvious to one skilled in the art at the time of the invention to have added the cavity of McFarland in the peritoneal dialysis apparatus of Kamen in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (co1. 1, lines 30-34) as implicitly taught by McFarland.

Furthermore, it is inherent in the disclosure of McFarland that the cavity is at least the valve displacement because in order for the lower surface of the bar to conform "to the contour of the surface of weir 35 in order to hold the diaphragm in leak-proof relationship with the weir when in closed position" (col. 4, lines 50-54).

In Reference to Claim 53

Kamen teaches:

A system for performing fluid administration (col. 1, lines 8-9) on a patient comprising a flexible membrane (Fig. 8, #59, 61) forming a valve seat (Fig. 8C, #72)

However, Kamen does not teach:

characterized by the fact that said membrane includes a clipping mechanism adapted to be reversibly attached to a moving actuator in such a way that the membrane movement can be controlled in a push and a pull operation mode.

McFarland teaches:

characterized by the fact that said membrane includes a clipping mechanism (Fig. 6, #39) adapted to be reversibly (col. 4, lines 62-65) attached to a moving actuator (Fig. 6, #33) in such a way that the membrane movement can be controlled in a push and a pull operation mode (col. 5, lines 23-29, 62-66).

It would have been obvious to one skilled in the art at the time of the invention to have included the clipping mechanism of McFarland in the peritoneal dialysis apparatus of Kamen in order to improve the diaphragm to extend diaphragm life and maintain proper mechanical action (co1. 1, lines 30-34) as implicitly taught by McFarland.

30. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of McFarland as applied to claim 22 above, and further in view of European Patent Application Publication EP 1 195 171 A2 to Suzuki, Minoru et al. (Suzuki).

In Reference to Claim 23

Kamen, as modified by McFarland, teaches:

A system according to claim 22 (see rejection above)

But does not teach a system wherein said membrane is molded.

Suzuki teaches wherein said membrane is molded (col. 9, lines 36-38).

It would have been obvious to one skilled in the art at the time of the invention to have used the molded membrane of Suzuki in the peritoneal dialysis apparatus of Kamen, as modified by McFarland, in order to improve the quality of the cassette and reduce the cost (col. 9, lines 38-40) as explicitly taught by Suzuki.

In Reference to Claim 24

Kamen, as modified by McFarland, teaches:

A system according to claim 23 (see rejection above) wherein said membrane is made out of any of the following materials: silicone, Kraton TM, Santoprene TM, polyurethane, Pebax TM or Biopure TM.

But does not teach a system wherein said membrane is made out of any of the following materials: silicone, Kraton TM, Santoprene TM, polyurethane, Pebax TM or Biopure TM.

Suzuki teaches wherein said membrane is made out of any of the following materials: silicone (col. 10, line 8), Kraton TM (thermoplastic elastomer col. 10, line 5), Santoprene TM (a polyolefin col. 9, line 56), polyurethane (col. 10, line 7), Pebax TM (thermoplastic elastomer or flexible polyamide col. 10, line 7) or Biopure TM.

It would have been obvious to one skilled in the art at the time of the invention to have chosen a material with particular properties, "a soft resin" (col. 9, line 56). See MPEP 2144.07.

In Reference to Claim 25

Kamen, as modified by McFarland, teaches:

A system according to claim 24 (see rejection above) wherein said membrane includes liquid tight joints (Kamen col. 7, lines 40-42).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kenneth Bomberg can be reached on 571-272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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LRW

/Kenneth Bomberg/
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